



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/815,820

04/02/2004

David Walter Wright

115623

8832

25944 7590 06/02/2008

OLIFF & BERRIDGE, PLC  
P.O. BOX 320850  
ALEXANDRIA, VA 22320-4850

EXAMINER

BOWERS, NATHAN ANDREW

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

06/02/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/815,820	<b>Applicant(s)</b> WRIGHT ET AL.	
	<b>Examiner</b> NATHAN A. BOWERS	<b>Art Unit</b> 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 07 March 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) 25-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>112304, 040204</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election with traverse of Group I, claims 1-24 in the reply filed on 07 March 2008 is acknowledged. The traversal is on the ground that there is no serious burden on the examiner to examine all the claims. This is not found persuasive because each group is drawn to a different classification and requires separate searching and consideration.

The requirement is still deemed proper and is therefore made FINAL.

Claims 25-47 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 07 March 2008.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

- 1) Claims 1, 4, 6-9 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Owen (WO 00/18226).

With respect to claims 1 and 9, Owen discloses an apparatus for holding an organ comprising a portable housing (Figure 2:65) and an organ support surface (Figure 2:66) designed to support the organ within the housing. Pages 7-10 indicate that a perfusion system is provided such that fluids are added to and removed from the housing using tubing in communication with openings positioned across the housing. The portable housing further comprises a closable air vent (Figure 11D:61) that functions as a pressure control valve capable of regulating pressure within the housing.

With respect to claims 4 and 11, Owen discloses the apparatus in claims 1 and 9 wherein the portable housing includes a lid and the pressure control valve is arranged in the lid. This is apparent from Figure 11D.

With respect to claims 6-8, Owen discloses the apparatus in claim 1 wherein the portable housing further comprises a pressure sensor that is referenced to a desired pressure. Page 11 states that a pressure sensor (Figure 2:P1) is used to control the pressure of medical fluid fed into an organ.

2) Claims 1, 4, 6-9 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Fahy (US 5586438).

With respect to claims 1 and 9, Fahy discloses an apparatus for holding an organ comprising a portable housing (Figure 1:11) and an organ support surface (Figure 1:13) designed to support the organ within the housing. Column 4, line 63 to column 5, line 49 indicate that a perfusion system is provided such that fluids are added to and removed from the housing using tubing in communication with openings positioned

across the housing. See also Figure 2. Column 4, lines 1-6 state that the portable housing further comprises a pressure control valve (Figure 1:199) capable of regulating pressure within the housing.

With respect to claims 4 and 11, Fahy discloses the apparatus in claims 1 and 9 wherein the portable housing includes a lid and the pressure control valve is arranged in the lid. This is apparent from Figure 1.

With respect to claims 6-8, Fahy discloses the apparatus in claim 1. Column 7, lines 39-56 further indicates that the portable housing further comprises a pressure sensor (Figure 1:124) that is referenced to a desired pressure.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3) Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over either Owen (WO 00/18226) or Fahy (US 5586438) each as applied to claim 1.

Owen and Fahy each disclose the apparatus set forth in claim 1 as set forth in the 35 U.S.C. 102 rejections above. Although Owen and Fahy each only describe the use of a single pressure control valve, it would have been obvious to utilize a plurality of closeable vents in both devices. The addition of extra venting mechanisms would involve no major structural reconfiguration of the Owen and Fahy devices, and would require only a minor duplication of parts that are well known in the art. See MPEP

2144.04. Additional pressure control valves would result in a more uniform removal of gases from the organ maintenance system.

4) Claims 3, 10, 13, 14 and 16-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Owen (WO 00/18226) or Fahy (US 5586438), and further in view of Eudailey (EP 0337677).

Owen and Fahy each disclose the apparatus set forth in the 35 U.S.C. 102 rejections above, however do not expressly disclose that the pressure control valves include a hydrophobic membrane.

Eudailey discloses a portable housing for accommodating tissues. The lid (Figure 1:10) provided over the housing includes a plurality of pressure control valves (Figure 3:36) each capable of venting gases contained within the housing. Eudailey further states that a hydrophobic membrane (Figure 3:34) is positioned across the vents.

Owen, Fahy and Eudailey are analogous art because they are from the same field of endeavor regarding tissue culture systems.

At the time of the invention, it would have been obvious to provide hydrophobic membranes across the closable vents disclosed by Owen and Fahy. Eudailey teaches that hydrophobic membranes are beneficial because they serve to retain critical fluids within an organ container while allowing the escape of gases. Eudailey further states that membranes advantageously prevent microorganisms and other particulate contaminants from entering the interior of the tissue housing.

5) Claims 5 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Owen (WO 00/18226) or Fahy (US 5586438) each as applied to claims 1 and 9, and further in view of Messier (US 5681740).

Owen and Fahy each disclose the apparatus set forth in claims 1 and 9 as set forth in the 35 U.S.C. 102 rejections above, however do not expressly disclose that a single housing is provided with a plurality of lids.

Messier discloses an apparatus for the storage and transportation of organs and tissues. The housing of the apparatus is in communication with a first lid (Figure 1:12) and a second lid (Figure 1:102). Each lid comprises a gas accessing means (Figure 1:150) comprising a closable vent.

Owen, Fahy and Messier are analogous art because they are from the same field of endeavor regarding organ holding containers.

At the time of the invention, it would have been obvious to provide either of the apparatuses of Owen and Fahy with multiple lid fixtures having multiple pressure control valves. Messier teaches that this arrangement is useful because it discourages contamination since an additional barrier is provided. Messier indicates that it is known in the art to utilize multiple lids comprising ports designed to interact with one another.

6) Claims 15 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Owen (WO 00/18226) or Fahy (US 5586438) each in view of Eudailey (EP 0337677) as applied to claims 13 and 22, and further in view of Messier (US 5681740).



Owen and Fahy each in view of Eudailey disclose the apparatus set forth in claims 1 and 9 as set forth in the 35 U.S.C. 103 rejections above, however do not expressly disclose that a single housing is provided with a plurality of lids.

Messier discloses an apparatus for the storage and transportation of organs and tissues. The housing of the apparatus is in communication with a first lid (Figure 1:12) and a second lid (Figure 1:102). Each lid comprises a gas accessing means (Figure 1:150) comprising a closable vent.

Owen, Fahy, Eudailey and Messier are analogous art because they are from the same field of endeavor regarding organ holding containers.

At the time of the invention, it would have been obvious to provide either of the apparatuses of Owen and Fahy with multiple lid fixtures having multiple pressure control valves. Messier teaches that this arrangement is useful because it discourages contamination since an additional barrier is provided. Messier indicates that it is known in the art to utilize multiple lids comprising ports designed to interact with one another.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The Yland (US 5326706) reference discloses an apparatus for holding organs that comprises multiple lids and pressure control vents.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NATHAN A. BOWERS whose telephone number is

(571)272-8613. The examiner can normally be reached on Monday-Friday 7 AM to 4 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on (571) 272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Beisner/

Primary Examiner, Art Unit 1797

/Nathan A Bowers/

Examiner, Art Unit 1797